Survey in the Emergency Department of Parents' Understanding of Cough and Cold Medication Use in Children Younger Than 2 Years

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Objectives: In August 2007, the Food and Drug Administration (FDA) released a public health advisory recommending that over-the-counter cough and cold medications (CCMs) not be used in children younger than 2 years. Our objective was to assess parents' awareness and understanding of the guidelines.

Methods: We surveyed caregivers of children younger than 2 years in the emergency department of an urban tertiary care military hospital where civilian patients are also treated. After completing the survey, caregivers received a handout explaining the FDA's recommendations.

Results: Our response rate was 99% (264/265). First-time parents constituted 45% (114/251) of responders. Education level was high school, 21%; some college, 36%; and college graduate, 40%. Thirty-one percent (77/247) were aware of the FDA guidelines. Of these 77, 44 (57%) reported the guidelines indicated CCMs were not safe in children younger than 2 years, and 18 (23%) said CCMs have caused death. Twenty-six percent (68/264) did not give CCMs to their children younger than 2 years, and 40% of these reported it was because of learning about the guidelines; 63% (165/264) reported CCMs were effective, 11% ineffective, and 27% did not know. Fifty-seven percent (151/263) reported CCMs were safe, 12% unsafe, and 31% unsure. Twenty-two percent (31/143) planned to use or continue to use CCMs in their children, 34% did not, 23% not sure, and 21% only if their doctor advised it.

Conclusions: The majority of caregivers were not aware of the FDA guidelines on CCM use in children younger than 2 years. Most thought CCMs were safe and effective.

Key Words: cough and cold medications, Food and Drug Administration guidelines, Public Health Advisory, infants, over-the-counter

(*Pediatr Emer Care* 2012;28: 883–885)

Americans have more than 1 billion upper respiratory tract infections each year, and children average 3 to 8 colds annually.[1] Over-the-counter (OTC) cough and cold medications (CCMs) include classes such as antihistamines, cough suppressants, decongestants, analgesics, expectorants, and sleep aids. They are widely used in children of all ages despite unproven efficacy or safety and regardless of labels recommending that parents seek physician advice for children younger than 2 years.[2] The most comprehensive review of pediatric fatalities from nonprescription CCMs over a 50-year period revealed that 103 deaths occurred in children younger than 12 years, and 77 cases (75%) involved a child younger than 2 years.[3] These OTC medications were used to treat a non–life-threatening, self-limited illness.

In August 2007, the US Food and Drug Administration (FDA) published a guideline recommending that OTC CCMs not be given to children younger than 2 years because of unproven safety and efficacy. Many parents are unaware of the FDA's recent public health advisory.[4] In 1 study of parents sitting in pediatricians' offices, 73% were aware of the FDA's recent recommendation against using these medicines in children younger than 2 years, 70% believed these products relieved symptoms, 68% did not believe they were dangerous, and 74% had them at home.[5] No report has published what proportion of parents visiting an emergency department (ED) know about the FDA's guideline and whether they believe the medications to be effective and safe.

The objective of our survey was to assess parents' awareness and understanding of the FDA's recent advisory on the use of CCMs in children younger than 2 years.

METHODS

We conducted a voluntary 14-question survey on a convenience sample of English-speaking parents or primary caregivers of children younger than 2 years in the ED of an urban tertiary care military hospital where civilian patients are also treated. Approximately 53,000 patients are treated annually, of which 50% are family members of active-duty military, retirees, or civilian patients.

Survey questions were piloted on a small sample and then revised. In an attempt to reduce bias, questions about CCM use were put at the beginning of the survey, and questions about the FDA guidelines were placed at the end to minimize influence on the usage questions by new knowledge of the guidelines. Trained research assistants were given a script for approaching and inviting participants to respond to the survey questions. They distributed and collected the paper surveys while the patients were in the waiting room and noncritical care areas of the ED at all hours from February to August 2010.

With the survey, we queried patients on the parents' use of CCMs in children younger than 2 years, the perceived safety and effectiveness of the medications, and knowledge of CCM ingredients and adverse effects and ended with the parents' awareness and knowledge of the content of the FDA's public health advisory. Some questions were multiresponse items. On

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Disclosure: The authors declare no conflict of interest.

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This study was presented as a poster at the American College of Emergency Physicians Scientific Assembly in Las Vegas, NV, September 2010.

There is no prior publication, conflict of interest, or copyright constraint. No funding was used for this study. The views expressed in this article are those of the authors and do not reflect the official policy or position of the Department of the US Air Force, Department of Defense, or the US Government.

ISSN: 0749-5161

Report Documentation Page

Form Approved
OMB No. 0704-0188

1. REPORT DATE	2. REPORT TYPE	3. DATES COVERED
01 SEP 2012	**N/A**	**-**

4. TITLE AND SUBTITLE	5a. CONTRACT NUMBER
Survey in the emergency department of parents' understanding of cough and cold medication use in children younger than 2 years	5b. GRANT NUMBER
	5c. PROGRAM ELEMENT NUMBER
6. AUTHOR(S)	5d. PROJECT NUMBER
Varney S. M., Bebarta V. S., Pitotti R. L., Vargas T. E.,	5e. TASK NUMBER
	5f. WORK UNIT NUMBER
7. PERFORMING ORGANIZATION NAME(S) AND ADDRESS(ES)	8. PERFORMING ORGANIZATION REPORT NUMBER
United States Army Institute of Surgical Research, JBSA Fort Sam Houston, TX	
9. SPONSORING/MONITORING AGENCY NAME(S) AND ADDRESS(ES)	10. SPONSOR/MONITOR'S ACRONYM(S)
	11. SPONSOR/MONITOR'S REPORT NUMBER(S)

12. DISTRIBUTION/AVAILABILITY STATEMENT
Approved for public release, distribution unlimited

13. SUPPLEMENTARY NOTES

14. ABSTRACT

15. SUBJECT TERMS

16. SECURITY CLASSIFICATION OF:			17. LIMITATION OF ABSTRACT	18. NUMBER OF PAGES	19a. NAME OF RESPONSIBLE PERSON
a. REPORT	b. ABSTRACT	c. THIS PAGE			
unclassified	**unclassified**	**unclassified**	**UU**	**3**	

completion of the survey, the research assistants gave participants an educational handout explaining the FDA's recommendations on CCM use in children younger than 2 years, along with relevant links to the FDA Web site. Data were analyzed using descriptive statistics. If an incomplete survey was returned, the completed questions were included in our analysis. Our institutional review board reviewed the study and exempted it. No protected health information was collected.

RESULTS

Two hundred sixty-four of 265 surveys were returned, giving an overall response rate of 99.6%. First-time parents constituted 114 (45%) of 251 responders, and 22 (8%) of 264 had 2 children younger than 2 years. Of 250 participants responding, the highest education level obtained included some high school in 7 (3%), a high school diploma or equivalent in 52 (21%), some college in 90 (36%), and a college degree (associate's, bachelor's, master's, or doctorate) in 101 (40%).

Seventy-seven (31%) of 247 responders were aware that the FDA had released a guideline on OTC CCM use in young children. Of these 77, 44 (57%) understood the guideline to say that CCMs were not safe in children younger than 2 years, 18 (23%) said these medications have caused death in this age group, 26 (33%) reported insufficient information existed so they should consult their physician before use, and 10 (13%) said that CCMs can be dangerous but if used appropriately were safe.

Among 264 responders, 68 (26%) did not give CCMs to their children younger than 2 years. In 60 parents of the 68 who gave a reason for not giving these medications, 24 (40%) attributed it to learning about the FDA guideline. Those who administered medications to their young children gave various drug classes including analgesics, antihistamines, antipyretics, cough suppressants, expectorants, and decongestants.

One hundred sixty-five (63%) of 264 responders reported that CCMs were effective, 29 (11%) reported they were ineffective, and 70 (27%) did not know. Of 263 participants responding on the safety of CCMs, 151 (57%) felt they were safe, 32 (12%) unsafe, and 80 (30%) did not know. One hundred fifty-two (58%) of 261 respondents were not aware that some cough and cold preparations contain more than 1 drug combined in 1 bottle, strip, or tablet.

With regard to speaking with a physician before administering medication to their children, 63 (25%) of 253 reported they asked every time, 63 (25%) asked sometimes, 69 (27%) inquired only if their child was ill, and 58 (23%) did not speak with a physician. On the frequency of seeking medical care for their child for a cough or viral cold, 27 (10%) of 259 said they did so every time, 137 (53%) did sometimes, 41 (16%) sought care only if their child was very sick, and 54 (21%) did not seek care for coughs and colds.

In response to how often parents give their children medicine to help them sleep when they have an upper respiratory tract infection, 185 of 263 (70%) said they did not give medications to help them sleep, 27 (10%) did give medications, 7 (3%) said only when they travel, and 44 (17%) reported only when the child was ill.

Parents reported 477 responses for possible adverse effects from CCMs: 187 (39%) sleepiness; 73 (15%), tachycardia; 66 (14%), diarrhea; 42 (9%), stomach ache; 27 (6%), rash; 20 (4%), seizures; 27 (6%), no adverse effects; 31 (7%), death; and 4 (1%), other.

Regarding reading the medication label before administration, the majority of 256 respondents stated they did every time (154, 60%), most of the time (35, 14%), or some of the time (32, 13%), 14 (6%) never, and 21 (8%) said not if it was a medication they use frequently.

Finally, of 143 respondents on the continued use of these medications, 31 (22%) plan to use or continue to use these medicines in their children younger than 2 years, 48 (34%) do not plan to use them, 33 (23%) do not know how they will respond, and 31 (21%) will use the CCMs only if approved by their physician.

DISCUSSION

Our study found that less than one third of parents and caregivers of children younger than 2 years were aware of the October 2007 FDA advisory recommending that CCMs not be given to these young children. This is an important finding because the majority of the population surveyed had some college experience or were college graduates. It suggests that the FDA advisory panel may need more intensive marketing to reach the parents regardless of their education level.

In addition, we determined that knowing about the guideline and knowing its content are unrelated. Just over one half of the small proportion of parents who were aware of the guideline was able to explain that the advisory recommended avoiding CCM use in children younger than 2 years because of safety concerns. Only one fourth of responders recognized that CCM use had caused death in this age group.

Many families have young children who develop common illnesses such as coughs and colds. Working or single parents (results of military deployments) often must use child-care centers where respiratory tract infections spread readily. Parents may use OTC cough and cold preparations for their children's comfort or for their own needs despite no proven efficacy or safety. This constitutes an additional problem—the perceived safety and effectiveness of the CCMs in these young children. More than one half of responders reported that these medications were safe, whereas almost two thirds stated that the medications were effective despite the lack of scientific evidence.[6] Moreover, even though most parents read the medication labels, the caregivers were unaware that many OTC CCMs are combination products. This could lead to problems if mixed with other medications.

Although one fourth of responders stated they did not give CCMs to their children younger than 2 years, few attributed it to learning about the FDA guideline. Before receiving the educational handout, only one third of responders said they would not give, or would not continue to give, these medications to their children younger than 2 years. Study participants commented that they were surprised by the information given to them after filling out the survey. Most did not know that these medications had been removed from the market for this age group. This is concerning because it could lead to caregivers using adult cough and cold medicine in younger children, thus increasing the risk of inappropriate dosing and adverse events.[7–9] Our study showed that a number of parents indicated that they had gained important information to help their families.

Other surveys done since the FDA recommendation have shown similar results. Hanoch et al[10] did a survey that ended 45 days after the FDA first announced its recommendations. They assessed parents' knowledge of the new FDA recommendations, whether they trusted the FDA, and if it influenced their decision to use OTC CCMs for their children younger than 2 years. Two thirds of parents were aware of the FDA guideline. Of these, 33% said they would continue to use OTC CCMs for their children, and 37% were not sure. Our survey occurred approximately 3 years after the FDA advisory and showed that

only one third of caregivers were aware of the guidelines. Hanoch et al[10] further showed that one third of parents surveyed could not identify active ingredients and tended to give more than 1 drug at a time, whereas 86% did not store these medicines in a safe place. Half of those surveyed were not sure whether to trust the FDA recommendations.

Lokker et al[8] collected survey data from 3 health care centers looking at caregiver understanding of dosing and usage of OTC CCMs in children younger than 12 months. Of 187 caregivers, 87% were the child's mother. Literacy and numeracy tests were done before the survey. Fifty percent of caregivers said they would use cough and cold medicine labeled specifically for infants just by looking at the front label. Caregivers were influenced by packaging style, text on the packaging, and graphics, such as teddy bears or infants on the packaging. Only 50% of caregivers were influenced by the dosing instructions that recommended physician consultation before use in children younger than 2 years and said they would use the medicine for their children.[8]

Our study has limitations. This was a single-center study in a military hospital and may not be generalizable to other settings. However, upper respiratory tract infections are common, and parents frequently seek care for their children experiencing them, so the military setting may not impact the study findings. Another limitation is the high proportion of college-educated study participants. It may seem logical that if an educated group is unaware of the FDA public health advisory, then a less educated sample could possibly be less aware of the FDA guideline. However, Vernacchio et al[7] found that CCM use was not strongly associated with personal and demographic factors including parental education. In addition, the survey design (order of questions, looking at the latter questions first) may have biased participants to be overcautious in their responses and may not reveal the true level of awareness of the FDA guideline. This would overestimate awareness of the FDA advisory. However, to reduce bias, we placed general parental practice questions about CCM use first and then ended with specific questions about knowledge of the FDA advisory. Moreover, the survey was anonymous, which should minimize bias. Finally, parent responses in the ED setting may not reflect responses in a less serious setting or in a non–health care environment.

In conclusion, the majority of caregivers were unaware of the FDA advisory recommending that OTC CCMs not be used in children younger than 2 years. Most thought these medications were safe and effective despite the lack of scientific evidence.

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